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NOTICE OF ALLOWANCE AND FEE(S) DUE

T5960	T596	6718/2008	EXAMINER
Casimir Jones, S.C.	DEVI, SARVAMANOALA J N		
440 Science Drive	ART UNIT	PAPER NUMBER	
Stutic 203	1645		
Madison, WI 53711	DATE MALE DE 07/18/2008		

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701.871	11/05/2003	Renfeng Guo	UM-08443	6716

TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE DIAGNOSIS AND TREATMENT OF SEPSIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	10/20/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR INSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as

maintenance fee notifica	tions.	lock I for any change of address)	N	ote: A certificate of	mailing can only be used f	varate "FEE ADDRESS" for or domestic mailings of the
			P	pers. Each additiona	I paper, such as an assignm	for any other accompanying ent or formal drawing, must
72960 Casimir Jones,	S.C.	3/2008	T.	Cer	tificate of Mailing or Tran	smission
440 Science Drive Suite 203			ac tr	dressed to the Mail insmitted to the USP	Stop ISSUE FEE address FO (571) 273-2885, on the	rst class mail in an envelope s above, or being facsimile date indicated below.
Madison, WI 53	711					(Depositor's name)
						(Signature)
			L			(Date)
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EXAM		ART UNIT	CLASS-SUBCLASS	۰,	\$1020	10/20/2008
DEVI, SARVA	MANGALA J N	1645	424-143100	_		
1. Change of correspond	ence address or indication	n of "Fee Address" (37	2. For printing on the	patent front page, lis	it	
CFR 1.363). Change of corresp	ondence address (or Cha	unge of Correspondence	(I) the names of up to 3 registered patent attorneys or agents OR, alternatively,			
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			(2) the name of a single firm thaving as a member a 2-registered attorney or agent) and the names of up to 2-registered patent attorneys or agents. If no name is listed, no name will be printed.			
3. ASSIGNEE NAME A	ND RESIDENCE DAT	A TO BE PRINTED ON	THE PATENT (print or	ype)		
PLEASE NOTE: Uni recordation as set fort	less an assignee is ident h in 37 CFR 3.11. Com	ified below, no assignee pletion of this form is NO	data will appear on the I a substitute for filing a	patent. If an assign n assignment.	ee is identified below, the	document has been filed for
(A) NAME OF ASSI	SNEE		(B) RESIDENCE: (CI	TY and STATE OR C	OUNTRY)	
Please check the appropr	iate assignee category o	r categories (will not be pr	inted on the patent):	☐ Individual ☐ Co	orporation or other private gr	roup entity Government
4a. The following fee(s)	are submitted:	41	. Payment of Fee(s): (P	ease first reapply ar	ny previously paid issue fee	shown above)
Issue Fee			A check is enclosed			
Publication Fee (N	to small entity discount	permitted)	Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).			
			overpayment, to De	posit Account Number	er (enclose	an extra copy of this form).
5. Change in Entity Sta	tus (from status indicate s SMALL ENTITY stat		D.b. Apolicant is no le	maer claiming SMAI	L ENTITY status. See 37 C	PFR 1 27(a)(2)
						the assignce or other party in
Authorized Signature						
Typed or printed name			Registration No.			
	ation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this bu 'irginia 22313-1450. DO	CFR 1.311. The informatic i U.S.C. 122 and 37 CFR c USPTO. Time will vary rden, should be sent to the D NOT SEND FEES OR (on is required to obtain on the collection is depending upon the interpretation of the complex o	-		nd by the USPTO to process) ing gathering, preparing, and ime you require to complete partment of Commerce, P.O. for Patents, P.O. Box 1450,

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440 Science I	Drive			ART UNIT	PAPER NUMBER	
Suite 203 Madison, WI 53711				1645 DATE MAILED: 07/18/200	8	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 616 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 616 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)	
10/701,871	GUO ET AL.	
Examiner	Art Unit	
S Dovi Ph D	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 133 and MPEP 1308.

- 1. This communication is responsive to Applicants' amendment filed 06/19/08.
- The allowed claim(s) is/are claims 26 and 27, now renumbered as claims 1 and 2 respectively.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDOMMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) Thereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

 DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2.
 Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08),
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date .
- 7. X Examiner's Amendment/Comment
- 8.

 Examiner's Statement of Reasons for Allowance
- 9. Other _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 06/19/08 has been entered.

Applicants' Amendment

 Acknowledgment is made of Applicants' amendment filed 06/19/08 in response to the final Office Action mailed 03/21/08.

Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Tanya Arenson in a telephonic interview on 16 July 2008.

This application has been amended as indicated below:

Claim 26 has been amended as indicated below:

- --Claim 26 (Currently amended). A method of treating sepsis in a subject suffering from sepsis, wherein said sepsis is selected from the group consisting of sepsis eaused by a <u>due to</u> grampositive bacteria <u>bacteremia</u> and sepsis eaused by a gram-negative bacteria <u>due to</u> gram-negative bacteria omnrising
- (a) providing a reagent capable of blocking C5a receptor, wherein said reagent is a monoclonal antibody that specifically binds to said C5a receptor; and
- (b) administering said reagent to said subject, wherein said subject's survival is prolonged.--

Status of Claims

Claim 26 has been amended via the amendment filed 06/19/08.

July, 2008

Claim 26 has been amended via this Examiner's amendment.

Claims 26 and 27 are pending and are under examination.

The Ward Declaration

5) Acknowledgment is made of Applicants' submission of the Ward declaration filed 06/19/08 under 37 C.F.R 1.132. The declarant states that none of the listed authors of the applied Huber-Lang reference other than Ward, Riedemann, Guo, Huber-Lang, and Sarma were involved with the instant invention.

Rejection(s) Withdrawn

- 6) The rejection of claims 26 and 27 made in paragraph 8 of the Office Action mailed 03/21/08 under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn upon further consideration and in light of the teachings of Hyde et al. and Hotchkiss et al. cited below.
- 7) The rejection of claims 26 and 27 made in paragraph 10 made in paragraph 8 of the Office Action mailed 03/21/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 8) The rejection of claims 26 and 27 made in paragraph 12 made in paragraph 8 of the Office Action mailed 03/21/08 under 35 U.S.C § 103(a) as being unpatentable over Huber-Lang et al. (The FASEB J. 16: 1567-1574, October 2002, already of record) in view of Werfel et al. (J. Immunol. 157: 1729-1735, 1996, already of record) or Rothermel et al. (Scand. J. Immunol. 52: 401-410, 2000, already of record) and Read et al. (J. Exp. Med. 182: 267-272, 1995), is withdrawn in light of the Ward declaration. See paragraph 5 above.

Relevant Art

- 9) The following references, not applied in any of the rejections currently, are pertinent to the subject matter of the invention.
- Hyde et al. (Infect. Immun. 58: 519-624, 1990) showed that the CLP model of sepsis is applicable both to Gram-positive and Gram-negative bacterial sepsis. See pages 621; and Tables 2 and 3.

 Hotchkiss et al. (PNAS 96: 14541-14546, 1999) taught that the 'CLP model employed in the present study is an extensively utilized model that is felt to be the most clinically relevant animal model of sepsis'. See right column on page 14545.

Remarks

- 10) Claims 26 and 27, now renumbered as claims 1 and 2 respectively, are allowed. The amendment to claim 26 has descriptive support in paragraphs [0005] and [0007] of the instant specification.
- 11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/ S. Devi, Ph.D. Primary Examiner AU 1645